UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE BRISTOL-MYERS SQUIBB CO. CVR SECURITIES LITIGATION	:	Case No. 1:21-cv-08255 (JMF)
		ORAL ARGUMENT REQUESTED

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED COMPLAINT

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PRELIMINARY STATEMENT

Plaintiffs' entire complaint depends on the unsupported premise that BMS never intended to permit the CVR milestones to be satisfied. Defendants' opening memorandum exposed the logical gap between the complaint's allegations and the inferences plaintiffs ask the Court to draw from them. The opposition does not bridge that gap; it widens it.

To obscure their failure to plead facts that would support their theory, plaintiffs' opposition melds together events occurring over the course of two years as if they all occurred at once. The joint proxy statement / prospectus was issued in February 2019 – *nine months* before BMS had any role in the FDA applications for liso-cel or ide-cel. Plaintiffs offer no plausible allegation that BMS intended to cause the CVR milestones to be missed then – or at any time. Plaintiffs assert that this intent can be inferred just from the terms of the CVR Agreement, which required timely FDA approval of three different new product applications for there to be any payment to CVR holders. But the joint proxy statement / prospectus disclosed those terms and explained the risk that the conditions to payment might not be met. Negotiating terms of complex contingent value rights – which plaintiffs admit bridged a valuation gap after "intense negotiations" with Celgene – is not a securities violation. Compl. ¶¶ 13, 81. Plaintiffs' speculation does not meet even basic pleading standards for their claims based on the joint proxy statement / prospectus.

Plaintiffs' alleged securities fraud claims depend on the same theory that BMS never intended to achieve the CVR milestones. But the opposition barely discusses the actual contents of the alleged misrepresentations – post-merger updates about the FDA approval process that plaintiffs do not contend were inherently false. Their attempt to reverse-engineer fraudulent intent by criticizing BMS's handling of the approval process is no more than impermissible fraud-by-hindsight. The complaint should be dismissed in its entirety.

ARGUMENT

I. ALL CLAIMS BASED ON THE JOINT PROXY STATEMENT / PROSPECTUS SHOULD BE DISMISSED.

A. The Challenged Statements Are Not Actionable.

1. The PSLRA Safe Harbor Applies.

Recognizing the impact that the PSLRA safe harbor has on their joint proxy statement / prospectus-based claims, plaintiffs bury the issue in their opposition. Pls. Opp. at 31-33. Their safe harbor arguments revolve around plaintiffs' conclusory allegation that BMS never intended to live up to its obligations under the CVR Agreement. None is persuasive.

First, contrary to plaintiffs' contention, *id.* at 31, the challenged statements were "classically forward-looking," as courts repeatedly have recognized (including Judge Engelmayer in dismissing similar CVR-related claims). *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 535 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016); *see, e.g.*, *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 758 (S.D.N.Y. 2018) (statements concerning expectations for FDA approval were "opinions, forward-looking statements, or both").

Plaintiffs seek to avoid this well-developed body of case law by asserting that the statements "relate[d] to then-existing facts and conditions." Pls. Opp. at 31. The only "then-existing fact" plaintiffs identify is defendants' supposed knowledge at the time of the joint proxy statement / prospectus that the CVRs were worthless because BMS allegedly had no intention of meeting the CVR milestones. *Id.* That is just another way of asserting that BMS "knew, based on present conditions, that the statements were false when made[,]" which confuses the question of whether a statement is forward-looking with the applicability of the safe harbor's "actual knowledge" prong. *E.g.*, *In re NovaGold Res. Inc. Sec. Litig.*, 629 F. Supp. 2d 272, 292 (S.D.N.Y. 2009). Whether that prong applies is a different question from whether the statements

were forward-looking, which they clearly were. *See Slayton v. Am. Express Co.*, 604 F.3d 758, 766 (2d Cir. 2010).[1]

Second, plaintiffs admit that their argument concerning the "actual knowledge" prong rests primarily on events months or years after the date of the joint proxy statement / prospectus. Pls. Opp. at 33. Post-merger developments far in the future do not establish that any defendant knew any statement in the joint proxy statement / prospectus was false in February 2019. A plaintiff's failure to identify "specific, *contemporaneous* reports or statements showing [d]efendants did not believe [statements] when they were made[]" renders forward-looking statements inactionable. *In re Nielsen Holdings PLC Sec. Litig.*, 510 F. Supp. 3d 217, 231 (S.D.N.Y. 2021) (emphasis added) (Furman, J.).

The only contemporaneous allegations plaintiffs identify in the opposition arise from the CVR Agreement itself. Plaintiffs assert that the condition to any payment obligation with respect to the CVRs – FDA approval of three separate new product applications before their contractual milestone dates – was "atypical." Pls. Opp. at 18, 33. But contract terms negotiated at arms'-length in merger negotiations with Celgene do not support unfounded speculation that BMS never intended to comply with those terms – or, by extension, the assertion that the defendants knew certain disclosures about the CVRs were false when made. To the contrary, the allegedly "atypical" terms were fully disclosed along with the estimated probability of just 45% that all three conditions to payment on the CVRs would be met. Compl. ¶¶ 158, 163; Proxy Stmt. at 68.

[1] Contrary to plaintiffs' assertion, defendants have not "waived" any materiality argument. Pls. Opp. at 32 & n.26. Defendants specifically noted that several statements identified in plaintiffs' footnote are immaterial. *See* App'x 1, Statement Nos. 9, 11-14, 16, 19, 22-24. But there is no need to assess the materiality of the challenged statements in the proxy statement (Statements 1-4) because they are subject to dismissal under the other two prongs of the safe harbor.

Third, plaintiffs' generalized arguments concerning the "meaningful cautionary language" prong collapse in view of the actual disclosures in the joint proxy statement / prospectus. Plaintiffs assert that a warning that the CVRs could be rendered "valueless" was not meaningful because it did not disclose that "[d]efendants planned to deliberately delay the FDA application process" and did not "convey that the then-actual value of the CVRs was $0." Pls. Opp. at 32; *see* Compl. ¶ 163, Proxy Stmt. at 50. This type of argument has been tried before, and rejected, because it "conflates the actual knowledge and meaningful cautionary language prongs of the PSLRA[.]" *In re Bemis Co. Sec. Litig.*, 512 F. Supp. 3d 518, 534 (S.D.N.Y. 2021); *see also Gray v. Wesco Aircraft Holdings, Inc.*, 454 F. Supp. 3d 366, 394 (S.D.N.Y. 2020), *aff'd*, 847 F. App'x 35 (2d Cir. 2021). Under plaintiffs' mistaken view, "an allegation of actual knowledge of falsity would suffice to deprive a forward-looking statement of the protections of [the] safe harbor even if there were meaningful cautionary language otherwise." *Gray*, 454 F. Supp. 3d at 394.

Plaintiffs' assertion that the risk factor warnings were "boilerplate" also is mistaken. Pls. Opp. at 32. Cautionary language is meaningful when, as here, it "expressly warned of . . . the risk that brought about plaintiffs' loss." *Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 359 (2d Cir. 2002). Just as in *Sanofi*, the proxy statement warnings that "'milestone payments, if any, under the CVRs are uncertain'" and subject to the risk that the milestones might not be achieved were meaningful. 87 F. Supp. 3d at 536; *see* Proxy Stmt. at 50 (providing similar warnings).

2. Plaintiffs Have Not Identified an Actionable Misstatement.

Plaintiffs' claims based on the joint proxy statement / prospectus also fail to allege any actionable misstatement or omission. The opposition confirms that the sole basis for plaintiffs' falsity argument is their implausible theory that defendants failed to disclose that BMS "intended to or did deliberately delay the FDA approval process for [l]iso-cel (and [i]de-cel) to avoid the

CVR payouts." Pls. Opp. at 25. The opposition further confirms there are no allegations supporting a plausible inference that BMS had such an intent in February 2019.

Plaintiffs argue that the all-or-nothing structure of the CVR Agreement "makes the most sense" only if one assumes BMS was "planning to delay FDA submission for at least one of the Milestone Drugs." Pls. Opp. at 26. But neither the complaint nor the opposition identifies any facts to back up that conjecture. The inference that plaintiffs ask the Court "to draw is too speculative even on a motion to dismiss." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 104 (2d Cir. 2007); *see also In re Adient plc Sec. Litig.*, 2020 WL 1644018, at *24 (S.D.N.Y. Apr. 2, 2020) (rejecting plaintiffs' "speculative allegations about 'what really happened'" as "insufficient to state a claim").

In addition, all of the challenged statements are "quintessential opinion statements" because they all concern "expectations and projections for the future." *Shreiber v. Synacor*, 832 F. App'x 54, 57 (2d Cir. 2020); *see* Compl. ¶¶ 158, 160-61, 163-64. There are no facts alleged to support plaintiffs' assertion that the statements "are not opinions because [d]efendants knew and failed to disclose that [l]iso-cel would not launch by year-end 2020 and that there was a 0% chance the CVRs would pay out because Defendants were deliberately slow-rolling the [l]iso-cel approval process." Pls. Opp. at 31. Nor was it possible in February 2019, nine months before the Celgene merger closing, for BMS to "deliberately slow-roll[] the [l]iso-cel approval process." *Id.*

As plaintiffs recognize, an opinion statement is not actionable if it "fairly aligns with the information in the issuer's possession *at [the] time*." *Tongue*, 816 F.3d at 210 (emphasis added) (quoting *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 189 (2015)). In this case, the complaint does not allege that any challenged statement in the joint proxy

statement / prospectus conflicted with information available to BMS or the other defendants in February 2019, when it was issued.

Plaintiffs' allegations based on later events are no more than fraud by hindsight. In the Second Circuit, "it is 'not sufficient . . . to allege that an opinion was . . . *not borne out by subsequent events*.'" *Villare v. Abiomed, Inc.*, 2021 WL 4311749, at *19 (S.D.N.Y. Sept. 21, 2021) (emphasis added); *see, e.g.*, *Lopez v. CTPartners Exec. Search Inc.*, 173 F. Supp. 3d 12, 40-41 (S.D.N.Y. 2016) (rejecting allegations defendant knew projection was false based on correction issued "a week later"). Plaintiffs assert that they have not alleged "fraud by hindsight" because the complaint alleges a "secret plan" to delay FDA approval of liso-cel, Pls. Opp. at 22, but they cannot infer a "secret plan" into existence based on alleged events occurring much later. *Stevelman v. Alias Research Inc.*, 174 F.3d 79, 85 (2d Cir. 1999).[2]

Finally, plaintiffs cannot base their proxy statement claims on an analyst report dated November 7, 2019. *See* Pls. Opp. at 30. Plaintiffs do not dispute that the report was neither a "registration statement" nor a "prospectus," so it cannot be the basis for a Securities Act claim. As for their claims under section 14(a) of the Exchange Act, plaintiffs misstate the holding in *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135 (2011), which requires an alleged "maker" of a statement to have "'ultimate authority' over its expression." *Zagami v. Cellceutix Corp.*, 2016 WL 3199531, at *6 (S.D.N.Y. June 8, 2016). Plaintiffs do not allege that here.

[2] The decision in *United States v. Goffer*, 721 F.3d 113, 124 (2d Cir. 2013), does not support plaintiffs' assertion that "[s]ubsequent acts are frequently probative as to intent." Pls. Opp. at 26. The court in *Goffer* addressed the admissibility of evidence concerning a criminal defendant's conduct after alleged insider trades (which it found "probative" but "not in itself sufficient" to establish knowledge of illegality). That opinion does not support plaintiffs' contention that fraud can be inferred at the pleading stage based on hindsight allegations.

B. Plaintiffs' Proxy Statement Claims "Sound in Fraud."

Plaintiffs' contention that their Securities Act and Exchange Act § 14(a) claims are subject to a lesser pleading burden is grounded in their unfounded assertion that the defendants "are not alleged to have acted fraudulently[.]" Pls. Opp. at 23. Their claims depend on the allegation that BMS never intended to meet all of the CVR milestones, Compl. ¶¶ 159, 162, 167, which is the type of accusation "classically associated with fraud[.]" *Rombach v. Chang*, 355 F.3d 164, 172 (2d Cir. 2004). Plaintiffs' invocation of the boilerplate disclaimer of fraud in their complaint does not change that conclusion. *See In re JP Morgan Chase Sec. Litig.*, 363 F. Supp. 2d 595, 635 (S.D.N.Y. 2005).

C. Plaintiffs' § 14(a) Loss Causation Arguments Are Impermissibly Speculative.

Plaintiffs identify no factual allegations in support of their mistaken contention that they have pleaded loss causation for their section 14(a) claim. Pls. Opp. at 35. Speculation that the CVR contingencies would have been met but for the alleged failure to disclose BMS's "secret plan" to slow-roll the FDA approval process is incapable of objective proof and therefore insufficient. Compl. ¶ 230; *see Gray*, 454 F. Supp. 3d at 404.

II. THE SECURITIES FRAUD CLAIMS ALSO SHOULD BE DISMISSED.

A. The Complaint Does Not Allege Any Actionable Misstatement.

1. None of the Challenged Statements Was False or Misleading.

Plaintiffs concede that the challenged post-merger statements were not inherently false or misleading. They argue instead that the alleged misrepresentations were false or misleading only when "taken together and in context[.]" Pls. Opp. at 22-23 (quoting *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 250 (2d Cir. 2016)). But considering the statements that way does not help plaintiffs meet the demanding burden for pleading falsity under the PSLRA. *See* 15 U.S.C.§ 78u-4(b)(1).

Plaintiffs admit their falsity claims rest on the repeated allegation that BMS made a "deliberate decision to slow-roll the [l]iso-cel (and [i]de-cel) approval process to ensure that the milestones would never be met[.]" Pls. Opp. at 23; *id.* at 25. As already discussed, however, there are no allegations of contemporaneous fact to support that supposition – even for the post-merger statements alleged in plaintiffs' securities fraud claims. No pleading deference is owed to plaintiffs' speculation about BMS's motive in negotiating the terms of the CVR Agreement, *ATSI*, 493 F.3d at 104, and hindsight criticisms of BMS's handling of the FDA approval process also do not permit a plausible inference of falsity. *See* Defs. Mem. at 24-25; *infra* at __-__.[3]

Recognizing this problem, plaintiffs shift their theory to argue that the challenged statements "misled investors into believing that [BMS] was diligently seeking FDA approval[,]" and that whether BMS was acting diligently "is a factual issue . . . ." Pls. Opp. at 26. But that is not what the complaint alleges. Instead, it alleges that *all* of the statements were false because BMS *never* intended to achieve all of the CVR milestones. *See* Compl. ¶¶ 168-206.

Plaintiffs devote a single sentence to their allegation that BMS "was deliberately submitting deficient regulatory submissions for [l]iso-cel (and [i]de-cel)." Pls. Opp. at 27. But plaintiffs allege that the FDA *accepted* the liso-cel application and granted it "Priority Review," Compl. ¶ 98, and there is no plausible allegation that BMS knew in advance that the FDA would request additional information regarding the CMC module for the liso-cel application (filed shortly after the merger) or that the agency would deem the information submitted in response to that request to be a "major amendment" resulting in a three-month delay to the FDA's decision deadline. *See id.* ¶¶ 100-01. Neither BMS nor any other defendant had to "be clairvoyant; they

[3] Given their central premise that BMS never intended to abide by the CVR Agreement, it is plaintiffs who give rise to the additional falsity pleading "requirement" that "the speaker knew the statement was false or misleading when made." Pls. Opp. at 24 n.22.

[were] only responsible for revealing those material facts reasonably available to them." *Sanofi*, 87 F. Supp. 3d at 543.

Plaintiffs' arguments based on an alleged failure to disclose the readiness of liso-cel manufacturing facilities for their FDA inspections fall short for similar reasons. Pls. Opp. at 28-29. There is no general duty to disclose interactions with the FDA, as the defendants previously observed. *See, e.g.*, *Sanofi*, 87 F. Supp. 3d at 541-42; Defs. Mem. at 26. When, as here, "no materially adverse action was taken by the FDA" after an inspection, and a sponsor makes "commitments to the FDA to correct" any identified issues, there is no duty to disclose preliminary inspection results. *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 52 (2d Cir. 1995).

Nor are there any well-pleaded allegations of fact to support plaintiffs' argument that BMS "had control over and knew for certain" their alleged "lack of preparation" would delay the FDA approval process. Pls. Opp. at 28. Plaintiffs do not, and could not, plausibly allege that BMS had any control over the FDA decision-making process. Nor could there be any plausible allegation that FDA comments after the facility inspections were the reason liso-cel was not approved before its milestone date. Not only does the complaint include allegations making clear that the inspections were delayed by "pandemic travel restrictions," Compl. ¶ 204 (quoting BMS press release), but plaintiffs' allegations also show that BMS responded to FDA's comments about the facility inspections promptly and *before* the liso-cel milestone date. *Id.* ¶¶ 113, 126.

Finally, and similarly, falsity challenges to statements discussing the potential impact of the pandemic on the timing of liso-cel approval also have no support in any factual allegations. Pls. Opp. at 29-30. Plaintiffs have not alleged any facts that conflict with the words used in the challenged statements, which merely cautioned that the pandemic *could* have an impact on the timing of FDA approval. Compl. ¶¶ 179, 188, 195, 198. As facts turned out, that caution was

warranted because the liso-cel facility inspections *were* delayed by pandemic travel restrictions. See *id.* ¶ 204 (quoting November 16, 2020 BMS press release: "The FDA was unable to conduct an inspection of a third-party manufacturing facility in Texas during the current review cycle due to travel restrictions related to the COVID-19 pandemic.").

2. Most Alleged Misrepresentations Were Forward-Looking Statements Protected by the PSLRA Safe Harbor.

Most of the statements challenged in plaintiffs' securities fraud claims were forward-looking statements about the ongoing FDA approval process or the anticipated timing of regulatory approval. *Sanofi*, 87 F. Supp. 3d at 535; *see* Defs. Mem. at 27 (identifying statements). The opposition does not identify any allegations in the complaint supporting an inference that the defendants made any of the challenged forward-looking statements with "actual knowledge" that it was false. Plaintiffs also do not contest that the forward-looking statements were identified as such, and, far from "boilerplate," Pls. Opp. at 32, BMS's cautionary language about those statements "consistently gave warnings that the FDA might not approve" liso-cel by the milestone date, and "no reasonable investor could have believed that there was no risk in this regard." *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 334 (S.D.N.Y. 2014); *see Sanofi*, 87 F. Supp. 3d at 536. The claims based on those statements should be dismissed for this reason alone.

3. Statements Concerning the Working Relationship with the FDA Are Not Actionable.

Plaintiffs similarly fail to identify any factual allegation that would support their contention that statements generally describing the status of the FDA approval process or reiterating BMS's intention to work with the FDA were materially false or misleading. *See* Pls. Opp. at 27; *see* Defs. Mem. at 28 (Statements 9, 11, 15, 16, 18, 23, 24). Such "indefinite statements of corporate optimism" are not actionable unless "the speaker knew that the contrary was true." *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 174 (2d Cir. 2020). The complaint does not plausibly

allege that any defendant knew that BMS was *not* committed to working with the FDA to obtain approval or that BMS was *not* actually working with the FDA towards that goal.

Plaintiffs also do not contest that the statements were opinions. They plainly were, and plaintiffs have failed to carry their burden to show that they did not "fairly align[]" with the information available to defendants at the time. *Omnicare*, 575 U.S. at 189.

B. The Complaint Does Not Plead a Strong Inference of Scienter.

1. Plaintiffs' Assertion That Defendants Were Motivated to Avoid Payment on the CVRs Lacks Any Factual or Logical Support.

The opposition confirms that plaintiffs' principal allegation of a "motive" to commit securities fraud was for BMS to avoid any payment under the CVR Agreement. Pls. Opp. at 18-20. But that is neither "cogent" nor "compelling," and it does not support the required "strong inference" of scienter. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007); 15 U.S.C. § 78u-4(b)(2)(A).

As plaintiffs themselves allege, the CVR Agreement required BMS to use "diligent efforts" (as defined in the agreement) to obtain timely approval of liso-cel and the other two product candidates. Compl. ¶¶ 16, 88. If BMS deliberately had scuttled the FDA approval process, or even "slow-rolled" it, as plaintiffs allege, then BMS would have faced a claim for breach-of-contract damages equal to (at least) any amounts saved in avoided payments to CVR holders. Plaintiffs' response proves too much. Pls. Mem. at 18 n.13. It is not just that BMS would have faced "negative consequences" if plaintiffs' imaginary facts were reality; rather, the "negative consequences" for BMS would have likely negated any possible gain. There can be no "strong inference" of scienter when "plaintiff's view of the facts defies economic reason." *In re AT&T/DirecTV Now Sec. Litig.*, 480 F. Supp. 3d 507, 533 n.26 (S.D.N.Y. 2020).

Plaintiffs separately argue that "[t]he most logical inference" to be taken from BMS's decision not to buy back CVRs when they were trading at a discount is that it "knew its delaying tactics would eventually render the CVRs worthless[.]" *Id.* at 18-19. But the complaint offered a more plausible explanation: BMS wanted to avoid any appearance that it was exploiting the obvious "information asymmetry" between itself and CVR holders. Compl. ¶ 92. Plaintiffs cite no legal authority for the claim that failure to buy back securities supports an inference of scienter; in fact, courts have held the opposite. *See Tyler v. Liz Claiborne, Inc.*, 814 F. Supp. 2d 323, 337-38 (S.D.N.Y. 2011).

Finally, the Court should reject plaintiffs' attempt to infer a motive based on an assertion that the individual defendants were not adequately incentivized to achieve the CVR milestones. Pls. Mem. at 19. Plaintiffs again cite no legal authority to support that proposition, which makes no sense in any case. If financial motives "generally possessed by most corporate directors and officers" cannot support an inference of scienter, *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001), then the *absence* of such incentives also must be insufficient. [4]

2. Plaintiffs' Speculative Allegations of Conscious Misbehavior or Recklessness Do Not Give Rise to the Required "Strong Inference."

Plaintiffs' allegations of conscious misbehavior or recklessness are based not on "circumstantial evidence" but on self-serving speculation about the meaning of a series of disparate events culminating in FDA approval of liso-cel 36 days after its milestone date. Pls. Opp. at 11-13.

[4] Plaintiffs improperly attempt to amend their complaint by asserting for the first time that BMS's stock price rose in the 15 days after BMS announced that the CVR Agreement was terminated. Pls. Opp. at 19. But in any event, there is no allegation that any defendant sold BMS stock during that period and, by January 29, 2021, BMS's stock price was *lower* than the closing price on January 4, 2021. *See* https://tinyurl.com/2p9yjc9m.

Plaintiffs' theory that this near-miss was the product of a scheme hatched in early 2019 – long before the emergence of COVID-19 – is both facially absurd and factually unsupported.

To plead "strong circumstantial evidence" of scienter, a complaint must allege "conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Gissin v. Endres*, 739 F. Supp. 2d 488, 503 (S.D.N.Y. 2010). That requires allegations of: "(1) *specific* contradictory information [that] was available to the defendants (2) *at the same time* they made their misleading statements." *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 588 (S.D.N.Y. 2011) (emphasis in original). Where, as here, "there is no evidence of motive, [] the strength of the circumstantial allegations must be correspondingly greater." *Marcu v. Cheetah Mobile Inc.*, 2020 WL 4016645, at *7-8 (S.D.N.Y. July 16, 2020).

Plaintiffs do not identify any conflicting information allegedly available to BMS or the three individual defendants at the time of alleged setbacks in the FDA approval process that would support their overarching theory that those setbacks were the product of fraud. Pls. Opp. at 11-13. At best, plaintiffs allege "corporate mismanagement," far below the level of intent necessary for a securities fraud claim. *E.g.*, *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 562 (S.D.N.Y. 2014).

The after-the-fact opinions of plaintiffs' "FDA Biologics Expert" do not cure this fundamental pleading problem. *See* Pls. Opp. 14-15. The decision in *Ong v. Chipotle Mexican Grill, Inc.*, 294 F. Supp. 3d 199 (S.D.N.Y. 2018), is directly on point. The plaintiffs in *Ong* incorporated into their complaint the opinions of a food industry safety expert to bolster allegations that Chipotle's alleged deviations from industry standards amounted to securities fraud. *Id.* at 222. Noting that "opinions cannot substitute for facts under the PSLRA," the court not only struck the expert declaration attached to the complaint but also refused to "consider any conclusory

allegations . . . based on the Declaration." *Id.* at 223-24 (quoting *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 285-86 (5th Cir. 2006)); *see also Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 354 (2d Cir. 2022) (quoting *Blackwell* with approval).

Contrary to plaintiffs' arguments, *Ong* cannot be distinguished on the ground that it did not concern allegations in the body of the complaint. The declaration in *Ong* was incorporated into the pleading. If anything, plaintiffs' allegations of an unidentified "FDA Biologics Expert" are even less reliable than the opinions in *Ong*, which were presented in a sworn statement that laid out the basis for the stated opinions. The supposed expert's "opinions" here are conclusory and anonymous hindsight views about how things should have been done. *See* Compl. ¶¶ 4-5, 20, 22-23, 30, 96, 99-101, 108-16, 120, 121-26, 214. They are entitled to no weight or deference.

Consideration of those opinions would "not lead to a different result," in any event. *Sjunde AP-Fonden v. Gen. Elec. Co.*, 2021 WL 311003, at *9 (S.D.N.Y. Jan. 29, 2021). They are offered only to support plaintiffs' claims that BMS's handling of the FDA approval process deviated from industry standards, but "[f]ailure to follow industry standards . . . is not itself sufficient to support scienter." *Tung v. Bristol-Myers Squibb Co.*, 412 F. Supp. 3d 453, 461 (S.D.N.Y. 2019), *aff'd sub nom. Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343 (2d Cir. 2022).[5]

Allegations concerning eight "confidential witnesses" – seven of whom were employees of Lonza, not BMS – also fail to support the required "strong inference." Pls. Opp. at 16. Plaintiffs do not explain how any "confidential witness" was "in a position to know[]" anything about what the individual defendants knew about the Lonza facility's readiness for inspections. The witnesses' apparent lack of knowledge renders their allegations irrelevant to any scienter analysis.

[5] Plaintiffs' comparison of BMS's experience with that of a competitor seeking approval of Tecartus, a competing product candidate, sheds no light on any claim concerning liso-cel, ide-cel, or any defendant's state of mind. Pls. Opp. at 14, 17.

See, e.g., *Miao v. Fanhua, Inc.*, 442 F. Supp. 3d 774, 799 n.19 (S.D.N.Y. 2020) ("[W]here a complaint relies on information from a CW to establish scienter, the complaint must describe the nature of the CW's contact with the individual defendants that would be probative of defendants' mental state."). To the extent that they shed any light on the issues, the "confidential witness" allegations show that BMS was focused on resolving any operational issues at the facility and pressing toward FDA approval of liso-cel. *See* Defs. Mem. at 25-26, 33-34.

C. The Complaint's Loss Causation Allegations Are Inadequate.

Plaintiffs' loss causation arguments myopically focus on declines in the price of the CVRs following updates on the FDA approval process that plaintiffs have not tied "to a corrective disclosure regarding the falsity" of any previous statement. *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 175 (2d Cir. 2005). Plaintiffs' arguments also ignore that there was no revelation of a "concealed risk." *Id.* at 173. BMS repeatedly disclosed the risk that the FDA might not approve liso-cel by its CVR milestone date. There is no basis plausibly to infer that the allegedly corrective disclosures "revealed fraud to the market"; instead, the plausible inference is that the disclosures accurately reported developments in the FDA approval process that resulted in "concomitant market dissatisfaction," which "is simply not enough[]" to allege loss causation. *Born v. Quad/Graphics, Inc.*, 521 F. Supp. 3d 469, 494 (S.D.N.Y. 2021).

III. THE "CONTROLLING PERSON" CLAIMS SHOULD BE DISMISSED.

Plaintiffs' failure to allege a primary violation also requires dismissal of the "controlling person" claims under Securities Act § 15 and Exchange Act § 20(a). *JP Morgan Chase Co.*, 553 F.3d at 206-07; *ATSI*, 493 F.3d at 108.

CONCLUSION

For the foregoing reasons and those stated in defendants' opening memorandum, the complaint should be dismissed in its entirety.

Dated: New York, New York
June 16, 2022

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